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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|------------------|-------------|----------------------|-------------------------|------------------|
| 10/030,578       | 04/29/2002  | L.Brian Starling     | 4141-2-PUS              | 9225             |
| 22442            | 7590        | 03/31/2005           | EXAMINER                |                  |
| SHERIDAN ROSS PC |             |                      | DAVIS, RUTH A           |                  |
| 1560 BROADWAY    |             |                      | ART UNIT                | PAPER NUMBER     |
| SUITE 1200       |             |                      | 1651                    |                  |
| DENVER, CO 80202 |             |                      | DATE MAILED: 03/31/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

LD

|                              |                 |                 |  |
|------------------------------|-----------------|-----------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |  |
|                              | 10/030,578      | STARLING ET AL. |  |
|                              | Examiner        | Art Unit        |  |
|                              | Ruth A. Davis   | 1651            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 15-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/02/8/02</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1 – 14 in the reply filed on January 13, 2005 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 – 43 are pending; claims 15 – 43 have been withdrawn as being drawn to non-elected subject matter; claims 1 – 14 have been considered on the merits.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to a composition comprising a polymer, however is rendered vague and indefinite for reciting “and” in line 3 because it is unclear if each of the polymers must be present in the composition to meet the limitation of the claim, or if only one of the polymers must be present.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Radin et al. (WO 97/41842).

Applicant claims a composition comprising hollow calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter and the bone mixture comprises bone tissue or bone by products. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Lemons (US 5273964 A).

Applicant claims a composition comprising hollow calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products at about 5 – 95% or 50 – 75% of the composition. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof.

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Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the compositions comprising the claimed amounts of bone mixture. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of biologically active molecules in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell of Radin. Furthermore, although Radin does not teach the microstructures comprising each of the claimed calcium materials, it would have been obvious to one of ordinary skill in the art to use any of the claimed materials since they were routinely used in such compositions. In support Lemons teaches compositions comprising calcium particles wherein the particles are made from tricalcium phosphate (tribasic calcium phosphate) and/or hydroxylapatite (abstract). Thus, such materials were well known in the art to be equivalent substitutes used for the same purpose. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to substitute any of the claimed calcium containing materials in the composition of Radin with a reasonable expectation for successfully obtaining an effective calcium shell.

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9. Claims 1 – 3 and 7 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin in view of Gerhart et al (US 5085861 A).

Applicant claims a composition comprising hollow calcium containing microstructures and a bone mixture; wherein the microstructures are about 0.5 – 6 mm in diameter; and the bone mixture comprises bone tissue or bone by products. The calcium containing microstructure comprises hydroxyapatite, tribasic calcium phosphate, dicalcium phosphate, tetracalcium phosphate, calcium carbonate, calcium oxide, glass containing calcium phosphate or a mixture thereof. The composition further comprises a bonding agent that is a polymer selected from polyactic acid, polyglycolic acid, polycaprolactone, poly alpha hydroxyl esters, polyphosphatzenes, polyanhydrides and/or polypropylene fumarate; or a bonding agent is a calcium containing cement. The bonding agent is present at about 5 – 75% or 10 – 50% of the composition. The calcium containing cement is calcium phosphate, calcium sulfate or a mixture thereof, specifically calcium sulfate.

Radin teaches compositions comprising hollow calcium phosphate containing glass shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). The particles vary in size from about 50 mcm – 5 mm (p.6).

Radin does not teach the composition further comprising a bonding agent that is one of the claimed polymers or calcium containing cements, or wherein the cement is present at the claimed amounts. However Radin specifically teaches that the hollow particle compositions are used for filling or repairing bone defects (p.4,9).

Gerhart teaches that cements are well known and commonly used in compositions for repairing and fixing bone defects (col.1 line 10-36). Gerhart also teaches compositions for bone repair/fixation comprising calcium phosphate particles combined with a cement composition (or bonding agent) and calcium salts. Specifically, Gerhart teaches that the calcium particles are incorporated with polymers, allowing for superior fixation (col.2 line 22-35). The polymers used include polyesters, polyanhydrides, and/or polypropylene fumarate (col.4 line 35-52, col.5 line 1-8). Gerhart additionally teaches that the cement compositions comprise calcium sulfate or calcium phosphate (col.6 line 40-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Gerhart to include the claimed cements or polymers as a bonding agent in the composition of Radin, for its known use in bone repair compositions, and its advantage of superior fixation as disclosed by Gerhart. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Gerhart to include any of the claimed cements or polymers in the compositions of Radin with a reasonable expectation for successfully obtaining the calcium shell composition of Radin.

While the references do not teach the claimed amounts of cement, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of such active ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of cement with a reasonable expectation for successfully obtaining the composition obtained by the combined teachings of Radin and Gerhart.



### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 – 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 3, 5 and 7 – 8 of U.S. Patent No. 6210715 in view of Radin.

Patent 6210715 claims a biomedical implant composition comprising a hollow calcium phosphate microbead made from hydroxylapatite, tricalcium phosphate (tribasic calcium phosphate), or other calcium phosphate material; combined with a biological coating, that is about 100 mcm – 6mm in diameter (claims 1-3,5,7,8).

Although the claims do not recite a bone mixture, bone tissue or by-product as the biological coating, Radin teaches compositions comprising hollow calcium phosphate shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8) wherein the particles vary in size from about 50 mcm – 5 mm (p.6). At the time of the claimed invention, one of ordinary skill in the art would have been

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motivated by Radin to use bone mixtures in the compositions of the patent claims, since both compositions are used for biomedical bone implant and repair.

12. Claims 1, 3, 6 – 7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 11, 20 and 31 of U.S. Patent No. 6358532 in view of Radin.

Patent 6358532 claims a biomedical implant composition comprising a hollow microbead that is a calcium phosphate material combined with a biological coating; and a cementing agent (claims 1,8,11,20,31).

Although the claims do not recite a bone mixture, bone tissue or by-product as the biological coating, Radin teaches compositions comprising hollow calcium phosphate shells (abstract) that are combined with biologically active molecules such as BMP or collagen (bone mixture, tissues or by-products) (p.8). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Radin to use bone mixtures in the compositions of the patent claims, since both compositions are used for biomedical bone implant and repair.

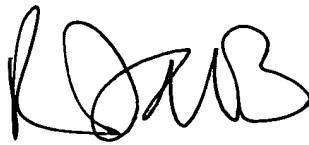
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis  
March 23, 2005  
AU 1651

A handwritten signature in black ink, appearing to read 'R Davis', is positioned to the right of the typed name and date.